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Gilead, Janssen extends HIV drug partnership

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Singapore: Gilead Sciences has expanded its agreement with Ireland based Janssen for the development and commercialization of HIV drug, containing Gilead's tenofovir alafenamide (TAF) and emtricitabine, and Janssen's rilpivirine.

The original agreement was established in 2009 for the development and commercialization of Complera, marketed as Eviplera in the European Union, which combines tenofovir disoproxil fumarate, emtricitabine and rilpivirine in a once-daily tablet. Gilead will initiate Phase 3 studies of emtricitabine/rilpivirine/TAF in the coming months.

Pending the product's approval, Gilead will be responsible for the manufacturing, registration, distribution and commercialization of the regimen in most countries, while Janssen will distribute in approximately 17 markets.

TAF is a novel nucleotide reverse transcriptase inhibitor that has demonstrated high antiviral efficacy at a dose 10 times lower than Gilead's Viread (tenofovir disoproxil fumarate), as well as an improved renal and bone safety profile.

"We believe that TAF's efficacy and safety advantages may make it a strong backbone of new fixed-dose combinations and single tablet regimens," said Mr Norbert Bischofberger, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Gilead is pleased to continue its collaboration with Janssen to bring improved treatment options to patients living with HIV."

Gilead and Janssen also have amended a licensing agreement for the development and commercialization of a once-daily single tablet regimen for HIV containing Gilead's TAF, emtricitabine and cobicistat, and Janssen's darunavir. Under the amended agreement, Janssen will be responsible for further development of the regimen and, subject to regulatory approval, the manufacturing, registration, distribution and commercialization of the product worldwide.

TAF and TAF-based regimens are investigational products in the United States and have not yet been determined safe or efficacious in humans.